

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

GILEAD SCIENCES, INC.,

Plaintiff/Counterclaim-Defendant,
v.

SIGMAPHARM LABORATORIES, LLC,

Defendant/Counterclaim-Plaintiff.

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Civil Action No. 10-4931 (SDW) (MCA)

OPINION

March 31, 2014

WIGENTON, District Judge:

This matter comes before the Court by way of Motion of Defendant Sigmapharm Laboratories, Inc. (“Sigmapharm” or “Defendant”) for Attorney’s Fees Pursuant to 35 U.S.C. § 285 and Federal Rule of Civil Procedure 54. (Dkt. No. 207). Plaintiff Gilead Sciences, Inc. (“Gilead”) opposes this Motion. (Dkt. No. 210). This matter was decided without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, Defendant’s Motion for Attorney’s Fees is **DENIED**.

I. BACKGROUND AND PROCEDURAL HISTORY

This case involved a Hatch-Waxman patent infringement action relating to a chemical compound called adefovir dipivoxil (“AD”), which is an active pharmaceutical ingredient used in the treatment of hepatitis B. AD is protected by two United States patents assigned or licensed to Gilead, namely U.S. Patent No. 5,663,159 (“the ’159 patent”) and U.S. Patent No. 6,451,340 (“the ’340 patent”). Gilead sells AD tablets under the brand name HEPSERA®. These patents were approved on September 20, 2002 by the U.S. Food and Drug Administration (“FDA”). In June 2010, Sigmapharm submitted an Abbreviated New Drug Application (“ANDA”) No. 202051, seeking approval from the FDA to manufacture and sell a generic version of Gilead’s

HESPERA® 10-milligram tablets. On September 24, 2010, Gilead filed its Complaint, alleging infringement of the '159 patent and the '340 patent (collectively "Patents-In-Suit"), as well as invalidity based on prior art. (Dkt. No. 1, Compl.). Gilead asserts, inter alia, that Sigmapharm's proposed AD product will infringe the Patents-In-Suit. On December 1, 2011, this Court held a Markman Hearing in this matter, and subsequently on May 31, 2012, the Court issued its opinion regarding the related claim constructions. On December 11, 2012, Gilead filed its Amended Complaint. (Dkt. No. 141.) On December 20, 2012, Gilead filed a Motion to Dismiss Defendant's Sixth Counterclaim and to Strike Defendant's Sixth Affirmative Defense Directed to Inequitable Conduct. (Dkt. No. 148.) On March 1, 2013, this Court denied Gilead's Motion to Dismiss without prejudice subject to the right to renew as an in limine motion prior to trial or as otherwise directed by the Court. (Dkt. No. 163.)

On or about March 15, 2013, Gilead executed and provided Sigmapharm with an unconditional and irrevocable covenant not to sue for infringement of the Patents-In-Suit. This covenant permits Sigmapharm to manufacture, produce, and sell the exact same proposed ANDA product under the same conditions set forth in Sigmapharm's original ANDA. On March 22, 2013, Gilead submitted its final Motion to Dismiss the current action, requesting that all claims be dismissed with prejudice, including any claims for attorney's fees from Sigmapharm. (Dkt. No. 170). On October 8, 2013, this Court ordered dismissal with prejudice for all claims and counterclaims, but permitted Sigmapharm to file a motion for attorney's fees under 35 U.S.C. § 285. (Dkt. No. 206).

Subsequently, on October 23, 2013, Sigmapharm filed the instant motion for attorney's fees claiming that this case is "exceptional" within the meaning of 35 U.S.C. § 285. (Dkt. No. 208). Sigmapharm argues that the case is "exceptional" because Gilead filed a patent

infringement suit on patents and claims that it knew to be invalid and/or unenforceable, and because it continued litigation even after it was clear it could not succeed. Gilead, on the other hand, contends that it had a legitimate basis for asserting and maintaining its infringement claims for both patents, and that these patents were both valid and enforceable at the time the litigation was instituted and that they remain valid and enforceable today.

II. LEGAL STANDARD

The general rule, known as the “American Rule,” is that “each party bears its own costs.” Refac Int’l, Inc. v. IBM Corp., et al., 710 F. Supp. 569, 570 (D.N.J. 1989); Machinery Corp. of Am. v. Gullfiber AB, 774 F.2d 467, 471 (Fed. Cir. 1985). A statutory exception to this rule can be found in 35 U.S.C. § 285, which provides: “[t]he court in exceptional cases may award reasonable attorneys’ fees to the prevailing party.” This provision “is normally invoked only at the end of litigation.” SL Waber, Inc. v. Am. Power Conversion Corp., 135 F. Supp. 2d 521, 527 (D.N.J. 1999). “The legislative history of § 285 indicates that Congress intended, even after trial, that it be used sparingly, since it represents a departure from the usual rule that counsel fees are not awardable to the prevailing party in an action at law, and the broad policy against allowing costs to be erected as an undue barrier to litigation.” Id. Moreover, it “is limited to circumstances in which the award of fees is necessary ‘to prevent a gross injustice.’” Aspex Eyewear Inc. v. Clariti Eyewear, Inc., 605 F.3d 1305, 1314 (Fed. Cir. 2010) (citation omitted).

Overall, it is within the discretion of the court to award fees and expenses. See Machinery Corp. of Am., 774 F.2d at 471. “Only after the prevailing party has established the exceptional nature of the case by clear and convincing evidence should the district court decide whether or not to make the award.” Id. However, even if the Court finds the case to be

exceptional, it still may decline to award fees based on the totality of the circumstances. See ADM Corp. v. Speedmaster Packing Corp., 525 F.2d 662, 664 (3d Cir. 1975).

Federal Rule of Civil Procedure 54(d) permits the parties to request and recover attorneys' fees after showing entitlement to such an award.

III. ANALYSIS

A. Whether Sigmapharm is a "Prevailing Party"

First, the court must determine whether the party seeking fees and expenses is the "prevailing party." Defendants who obtain a voluntary dismissal with prejudice are considered prevailing parties. See Highway Equip. Co. v. FECO, Ltd., 469 F.3d 1027, 1035 (Fed. Cir. 2006); Newell v. Nagl Mfg. Co., No. 04-1875, 2007 WL 2033838, at *5 (D.N.J. July 11, 2007) (Wigenton, J.) (citation omitted). Gilead even concedes that "Sigmapharm may technically be considered the 'prevailing party' in this action." (Dkt. No. 210 at 7.) Thus, Sigmapharm has met the first requirement for obtaining attorney's fees.

B. Whether this Case is "Exceptional"

Second, § 285 requires that the prevailing party demonstrate by clear and convincing evidence that the case is "exceptional." See 35 U.S.C. § 285. "To be considered exceptional, the court must find egregious misconduct." Newell, 2007 WL 2033838, at *5. "Exceptional cases usually feature some material, inappropriate conduct related to the matter in litigation, such as willful infringement, fraud or inequitable conduct in procuring the patent, misconduct during litigation, vexatious or unjustified litigation, conduct that violates Federal Rule of Civil Procedure 11, or like infractions." Serio-US Indus., Inc. v. Plastic Recovery Tech. Corp., 459 F.3d 1311, 1321-22 (Fed. Cir. 2006); Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1034 (Fed. Cir. 2002) (citation omitted); Wedgetail, Ltd. v. Huddleston Deluxe, Inc., 576

F.3d 1302, 1304 (Fed. Cir. 2009) (collecting cases). “Absent misconduct in the litigation or in securing the patent,” a case is exceptional only if (1) it was brought in subjective bad faith, and (2) the case is objectively baseless. Serio-US Indus., Inc., 459 F.3d at 1322; Brooks Furniture Mfg., Inc. v. Dutailer Int’l, Inc., 393 F.3d 1378, 1381 (Fed. Cir. 2005).

Sigmapharm contends that this case is exceptional and that it is entitled to attorney’s fees because Gilead filed a patent infringement suit on patents that it knew not to be infringed, were invalid and/or unenforceable, and because Gilead failed to dismiss its claims once circumstances relating to the infringement changed during the litigation. Thus, Sigmapharm appears to argue that this case is exceptional because the litigation was both brought and maintained in bad faith and was objectively baseless, and due to misconduct by Gilead in the procurement of the ’340 patent. Gilead, on the other hand, contends that it had a legitimate basis for asserting and maintaining its infringement claims for both the ’159 and ’340 patents because both patents were valid and enforceable at the time the suit was filed, and remain valid and enforceable today.

As an initial matter, this Court notes that the issues of non-infringement and invalidity of Gilead’s patents were never reached in the underlying litigation. Rather, all of the claims and counterclaims were dismissed with prejudice when Gilead signed a covenant not to sue. For the reasons set forth herein, this Court finds that Sigmapharm has failed to establish by clear and convincing evidence that this case is “exceptional” within the meaning of 35 U.S.C. § 285. The underlying facts and background of this case do not support such a finding.

i. The ’159 Patent

With respect to the ’159 patent, Sigmapharm contends that the patent was invalid because it was clearly “obvious” due to the Holy 1989 reference. Gilead, on the other hand, contends that it had the right to sue Sigmapharm for infringement because the ’159 patent is presumed to be

valid and enforceable. See 35 U.S.C. § 282 (“A patent shall be presumed valid.”); McNiel-PPC, Inc. v. L. Perrigo Co., 337 F.3d 1362, 1372 (Fed. Cir. 2003) (reversing the grant of attorney’s fees, even where patent-in-suit was invalidated after trial, noting that “[a] patent owner has the ‘right to exclude others from making, using, and selling the invention and to enforce those rights until [its patents are] held invalid [or expire].’”) (citation omitted)). This Court agrees.

To begin, Gilead’s patents are presumed to be valid and enforceable. Microsoft v. i4i Ltd. P’ship, 131 S. Ct. 2238, 2246 (2011) (explaining that the presumption of validity remains unless and until the presumption is overcome with “clear and convincing evidence of error”) (citations omitted). Patent holders have a right to sue for infringement of their patents until its patent is held invalid or expires. McNiel-PPC, Inc., 337 F.3d at 1372. Moreover, “[t]here is a presumption that the assertion of infringement of a duly granted patent is made in good faith.” Brooks Furniture Mfg., 393 F.3d at 1382. As such, Gilead was well within its right to assert its claim for patent infringement against Sigmapharm.

Second, this Court is satisfied that the existence of the Holy 1989 reference does not make the assertion of patent infringement “objectively baseless,” nor was the case asserted in “bad faith.” Gilead notes that the Holy 1989 reference was cited on the face of the patent and was thus before the patent examiner during prosecution of the application, which was subsequently granted. See Glaxo Grp. Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (noting that the burden of proving invalidity by clear and convincing evidence “is ‘especially difficult’ when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution”) (citation omitted)). Based on this reference and the fact that the patent was issued, Gilead had no reason to question the validity of the

patent, let alone know that it was invalid. Accordingly, this Court concludes that Gilead had a good faith and objectively reasonable basis to assert patent infringement of the '159 patent.

Sigmapharm also contends that Gilead should have dismissed its remaining infringement allegations concerning the '159 patent after August 10, 2012, when Sigmapharm admitted that it infringed the claims of the '159 patent that read on adefovir dipivoxil. However, according to Gilead, Sigmapharm only stipulated to infringement of the bis-POM PMEA claims of the '159 patent. Gilead contends that after August 10, 2012, it continued to pursue infringement claims 2, 4, and 14-17 of the '159 patent, which were directed to mono-POM PMEA¹. As previously noted, patent holders, Gilead included, have a right to sue for infringement of their patents. To find that it was improper for Gilead to sue for infringement of the mono-POM PMEA claims of '159 patent would encroach upon Gilead's patent rights. McNiel-PPC, Inc., 337 F.3d at 1372.

Sigmapharm also contends that Gilead could not prove infringement of the remaining claims because Gilead itself did not test Sigmapharm's product for the presence of mono-POM PMEA. Gilead contends that it did not need to test Sigmapharm's product because Sigmapharm had already tested it, had concluded the product contained mono-POM PMEA, and had reported those results to the FDA. This Court finds that whether Gilead was or was not required to perform further testing does not demonstrate that the case was brought in bad faith or that it was objectively baseless, particularly where, as here, Gilead claims it relied on Sigmapharm's testing.

ii. The '340 Patent

Sigmapharm also contends that this case is "baseless" because Gilead filed for infringement of the '340 patent when it knew or should have known that the patent was invalid due to undisclosed prior sales. See 35 U.S.C. § 102 (A person shall be entitled to a patent unless, inter alia, "the claimed invention was . . . on sale . . . before the effective filing date of the

¹ Adefovir dipivoxil and mono-POM PMEA are prodrugs covered by the '159 patent.

claimed invention.”). Sigmapharm claims that Gilead’s purchase of massive quantities of crystalline AD from third parties, Raylo Chemicals and Quintilies, which occurred years before the critical date of July 25, 1996 for the ’340 patent, were invalidating commercial sales. Sigmapharm also alleges that Gilead had a duty to disclose these sales to the USPTO and failed to do so. Gilead, on the other hand, contends that the ’340 patent was valid and enforceable when it brought suit, and that it remains valid and enforceable today. Gilead also alleges that it had a subjective good faith basis as well as an objective basis for viewing any alleged “sales” of AD prior to the critical date as non-invalidating sales because they were made primarily for the purposes of experimentation.

A person is entitled to a patent unless, inter alia, “the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States.” Electromotive Div. of GMC v. Transp. Sys. Div. of GE, 417 F.3d 1203, 1209 (Fed. Cir. 2005) (citing 35 U.S.C. § 102(b)). In Pfaff v. Wells Elecs., Inc., 525 U.S. 55 (1998), the Supreme Court set forth a two-part test for application of the on-sale bar. First, the claimed invention must be the subject of a commercial sale. Pfaff, 525 U.S. at 67. Second, the claimed invention must be ready for patenting. Id. at 67-68. The first prong of the Pfaff test entails an assessment of whether the circumstances surrounding a pre-critical date sale objectively show that it was primarily made for experimentation. Electromotive, 417 F.3d at 1210. The Federal Circuit has explained that:

The question posed by the experimental use doctrine . . . is not whether the invention was under development, subject to testing, or otherwise still in its experimental stage at the time of the asserted sale. Instead, the question is whether the transaction constituting the sale was not incidental to the primary purpose of experimentation, i.e., whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation

of the facts surrounding the transaction, was to conduct experimentation.

Id. (quoting Allen Eng'g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1354 (Fed. Cir. 2002)). If the sale was primarily for experimentation rather than commercial gain, then the sale is not invalidating under § 102(b). Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1258 (Fed. Cir. 2001) (“Evidence that the . . . sale of the patented device was primarily experimental may negate an assertion of invalidity.”). In Allen Eng'g Corp. v. Bartell Indus., 299 F.3d 1336, 1353 (Fed. Cir. 2002), the Court set forth a list of factors that are instructive for determining commercial versus experimental uses:

(1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Id. (quotation and alteration marks omitted).

“A use may be experimental only if it is designed to (1) test claims features of the invention or (2) to determine whether an invention will work for its intended purpose—itsself a requirement of patentability.” Clock Spring, L.P. v. Wrapmaster, Inc., 560 F.3d 1317, 1327 (Fed. Cir. 2009); In re Omeprazole Patent Litig., 536 F.3d 1361, 1373-75 (Fed. Cir. 2008). “In other words, an invention may not be ready for patenting if claimed features or overall workability are being tested. But, there is no experimental use unless claimed features or overall workability are being tested for purposes of the filing of a patent application.” Clock Spring, 560 F.3d at 1327; EZ Dock v. Schafer Sys., 276 F.3d 1347, 1354 (Fed. Cir. 2002). “Indeed, the

experimental use negation of the § 102(b) bar only exists to allow an inventor to perfect his discovery through testing without losing his right to obtain a patent for his invention.” Clock Spring, 560 F.3d at 1327; EZ Dock, 276 F.3d at 1352. Clinical trials conducted to determine the efficacy of a drug candidate have been found to be an example of experimental use negation of the statutory bar. See Bayer Schering Pharma AG v. Barr Labs., Inc., No. 05-cv-2308, 2008 WL 628592 (D.N.J. Mar. 3, 2008). “If there is adequate proof that a device was sold primarily for experimentation, the first prong of Pfaff would not be met and it would be unnecessary to consider either whether the device was an embodiment of the claimed invention or whether the invention was ‘ready for patenting’ at the time of the sales.” Allen Eng’g, 299 F.3d at 1353.

Sigmapharm alleges that more than one year prior to the filing of the ’340 patent, Gilead directed Raylo Chemicals to manufacture multiple bulk lots of crystalline AD and purchased the resulting lots. Sigmapharm claims that these purchases began in September 1994, almost two years before the critical date and continued regularly through June 1996. Sigmapharm also contends that Gilead purchased over thirteen thousand (“13,000”) bottles of crystalline AD tablets from Quintilies. Sigmapharm further alleges that the invention claims in the ’340 patent were not only “ready for patenting” but were actually reduced to practice in 1993, well before Gilead began purchasing AD. According to Sigmapharm, these purchases negate any assertion that the prior sales and/or uses were for research purposes.

Gilead, on the other hand, contends that it had a subjective good faith basis as well as an objective basis for viewing any alleged “sales”/“purchases” of AD prior to the critical date as non-invalidating sales because they were made primarily for purposes of experimentation. Gilead argues that the four batches that Sigmapharm relies on were intended for clinical use and were used in clinical studies or in other “non-clinical research.” (Dkt. No. 210, at 16); (see also

Dkt. No. 210-7, Ex. 9, GH000474070, “A Review of Adefovir Dipivoxil Manufacturing at Raylo ARS,” (discussing the process development period and showing that Raylo lots 2166-A-2P and 2166-A-6P were “rejected for clinical use” for containing unacceptably high impurity levels and thus the batches were re-processed for “non-clinical research”; “[a]ll other batches were released for clinical use”); (Dkt. No. 210-8, Ex. 10, GH000403678, “Summary of Drug Substance Lots,” (showing that Raylo lots 2166-A-4P, 2166-A-5P and 2166-A-7P were for use in toxicology, clinical, and stability studies)). Gilead argues that the allegedly invalidating sales consist of transactions between Gilead and Raylo, whom Gilead contracted to manufacture AD for the purposes of the clinical tests and other studies. Gilead also claims that Sigmapharm has failed to provide any evidence regarding the sales from Quintiles. Furthermore, Gilead contends that the reason it needed a large quantity of drugs was to develop an FDA-compliant manufacturing practice and protocols to administer the drug to humans in clinical trials, but that does not mean that the purchases were “commercial” batches.

Based on the record, this Court finds that Sigmapharm has not demonstrated by clear and convincing evidence that the sales were commercial and invalidating. To the contrary, Gilead has put forth adequate proof that the prior sales/purchases were primarily for experimentation. This evidence negates the assertion of invalidity. Accordingly, this Court finds that Gilead had a subjective good faith basis as well as an objective basis for asserting claims of infringement of the '340 patent against Sigmapharm.

Sigmapharm also alleges that Gilead filed infringement claims relating to the '340 patent despite knowing it was unenforceable. Sigmapharm essentially argues that Gilead committed “inequitable conduct” in the procurement of the '340 patent. However, there has been no finding or stipulation of unenforceability, much less a finding that Gilead somehow knew that the '340

patent was unenforceable. Moreover, Sigmapharm's inequitable conduct claim was dismissed with prejudice by agreement of the parties. (Dkt. No. 206). To prove inequitable conduct, Sigmapharm would need to demonstrate, by clear and convincing evidence, that a person having a duty of candor to the PTO "misrepresented or omitted material information with the specific intent to deceive the PTO." Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011) (internal citation omitted). Sigmapharm has failed to allege that the '340 patent inventors or prosecuting attorneys acted with specific intent to deceive. Instead, Sigmapharm offers only that the purchases of AD were "made with the knowledge of inventors of the '340 patent and the prosecution team," and that they failed to disclose such purchases to the PTO. (Dkt. No. 208, at 19.) Sigmapharm cites to meeting minutes that were supposedly circulated to some of the inventors and attorneys responsible for prosecuting the '340 patent. However, the mere existence of such a document does not establish knowledge of any purchases. In addition, Sigmapharm deposed two of the '340 patent inventors, but never asked either of them why such purchases were not mentioned to the PTO. The evidence before this Court is insufficient to demonstrate that Gilead had a specific intent to deceive the PTO. Accordingly, this Court finds that Sigmapharm has failed to prove that Gilead committed inequitable conduct in procurement of the '340 patent.

Further, Sigmapharm contends that Gilead should have discontinued the litigation as to the '340 patent after Sigmapharm amended its Drug Master File ("DMF"). Originally, Sigmapharm imported a solid AD precursor, ADDMC, into the United States. Sigmapharm subsequently amended its manufacturing process whereby it contended that it would only import liquid ADDMC. However, based on the evidence before the Court, including letters to the FDA (Dkt. No. 210-11, Ex. 13) and Sigmapharm's Amended Answer (Dkt. No. 145), it appears that

Sigmapharm never abandoned its original process, which is why Gilead continued its litigation against Sigmapharm as to the '340 patent. Moreover, when Sigmapharm amended its DMF to add the amended manufacturing process, Gilead amended its Complaint accordingly. (See Dkt. No. 140, Amended Compl., at ¶¶ 35-48). This Court finds that, even after Sigmapharm amended its DMF, Gilead had both a subjective and objective good faith basis and an objective basis for maintaining its infringement claims with respect to the '340 patent.

Finally, Sigmapharm contends that the timing of the covenant not to sue is significant, as it arrived mere days before the scheduled depositions of seven of Gilead's experts for the '340 patent and two weeks after the Court denied Gilead's motion to dismiss Sigmapharm's claims of inequitable conduct for the '340 patent. Gilead, on the other hand, explains that it chose to terminate this lawsuit because the landscape of the hepatitis B market changed during the course of the litigation and by early 2013 it no longer made sense for Gilead to pursue this case. Gilead contends that there were better and more efficacious alternatives such as Viread® and another generic product that were on the doorstep of entering the market.

As previously discussed, it is within the court's discretion whether or not to award attorney's fees. Machinery Corp. of Am., 774 F.2d at 471; Badalamenti v. Dunham's, Inc., 896 F.2d 1359, 1364 (Fed. Cir. 1990). It is equally clear that the defendant bears the burden of proving, by clear and convincing evidence, that this case is exceptional. Badalamenti, 896 F.2d at 1364. There must be some finding of unfairness, bad faith, or inequitable conduct on the part of the plaintiff. Based on the evidence before this Court, Sigmapharm has failed to establish any misconduct on the part of Gilead during the litigation or in the procurement of its patents, or that the litigation was objectively baseless and brought in subjective bad faith. Accordingly, this Court finds that this case is not "exceptional" within the meaning of 35 U.S.C. § 285.

IV. CONCLUSION

Defendant has not met the exceedingly high burden of presenting clear and convincing evidence that this case is “exceptional” within the meaning of 35 U.S.C. § 285 warranting the imposition of attorney’s fees. Therefore, this Court **DENIES** Defendant’s Motion for Attorney’s Fees.

s/SUSAN D. WIGENTON
United States District Judge

cc: Hon. Madeline Cox Arleo, U.S.M.J
All Parties
Clerk